IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DAVID GIROUX, derivatively on behalf of ACER THERAPEUTICS, INC. Plaintiff, v. JASON AMELLO, STEVE ASELAGE, HUBERT BIRNER, JOHN M. DUNN, MICHELLE GRIFFIN, LUC MARENGERE, HARRY PALMIN, and CHRIS SCHELLING, Defendants, and ACER THERAPEUTICS, INC., Nominal Defendant.	**VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT** DEMAND FOR JURY TRIAL Case No.: 1:20-cv-10537

Plaintiff David Giroux ("Plaintiff"), by and through his undersigned counsel, derivatively on behalf of nominal defendant Acer Therapeutics, Inc. ("Acer" or the "Company"), submits this Verified Stockholder Derivative Complaint against the Individual Defendants (defined herein) as officers and/or directors of Acer for breaches of fiduciary duty, waste of corporate assets, and violations of Section 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). Plaintiff bases his allegations on personal knowledge as to his own acts, and on information and belief as to all other allegations, based upon investigation by counsel, including, but not limited to, a review and analysis of: (i) regulatory filings made by Acer with the United States Securities and Exchange Commission (the "SEC"); (ii) press releases issued and disseminated by Acer; (iii) a purported securities class action lawsuit filed in the United Stated District Court for the Southern District of New York, captioned *Sell v. Acer Therapeutics, Inc.*, Case No. 1:19-cv-06137-GHW (S.D.N.Y.)

(the "Securities Class Action"), alleging violations of the federal securities laws based on similar facts and circumstances as alleged herein; and (iv) other publicly-available information, including media and analyst reports, concerning Acer.

NATURE OF THE ACTION AND OVERVIEW

1. This is a stockholder derivative action that seeks to remedy wrongdoing committed by certain of Acer's officers and members of the Company's Board of Directors (the "Board") and their affiliates. Plaintiff seeks to remedy Defendants' violations of state and federal laws from September 25, 2017 through June 24, 2019 (the "Relevant Period") that have caused and continue to cause substantial monetary damages to Acer and other damages, including damages to its reputation and goodwill.

2. Acer is a pharmaceutical company focused on the acquisition, development, and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs. Acer's pipeline purportedly includes three clinical-stage candidates: EDSIVO™ ("EDSIVO" or "celiprolol") for the treatment of vascular Ehlers-Danlos syndrome ("vEDS") in patients with a confirmed type III collagen ("COL3A1") mutation; ACER-001—a fully taste-masked, immediate release formulation of sodium phenylbutyrate—for the treatment of various inborn errors of metabolism, including urea cycle disorders and Maple Syrup Urine Disease; and osanetant for the treatment of induced Vasomotor Symptoms where Hormone Replacement Therapy is likely contraindicated.

3. During the Relevant Period, Acer, to satisfy its need for cash to fund its operations, conducted two public offerings in December 2017 and August 2018, raising $12.56 million and $46 million, respectively.

4. In doing so, the Individual Defendants represented to Acer's investors that the Company purportedly had an "agreement" with the U.S. Food and Drug Administration (the

"FDA") that further clinical development beyond a study conducted in France, which was published in October 2010 (the "Ong Trial"), "is not needed" or "is not likely needed."

5. Contrary to the Individual Defendants' representations as to the likelihood of obtaining FDA approval for EDSIVO, the Ong Trial's data was fundamentally flawed, precluding FDA approval.

6. Further, the Individual Defendants misrepresented the Company's communications with the FDA regarding EDSIVO. In reality, Acer and the FDA did not reach an agreement that the Company would not need to conduct additional clinical studies beyond the already-completed Ong Trial.

7. The Individual Defendants also failed to disclose to investors that the FDA did not consider the Ong Trial an "adequate and well-controlled" trial based on the severe imbalance between the trial's experimental and control arms as to the number of patients confirmed as suffering from vEDS. Indeed, the mutation data revealed that the Ong Trial was biased and very underpowered, which was a serious hurdle to FDA approval.

8. Despite these detrimental facts, the Individual Defendants painted a rosy prospect for EDSIVO by stating that the Company was: (i) working collaboratively with the FDA; accelerating pre-commercial activities for EDSIVO; (ii) expanding senior-level commercial and medical affairs teams; and (iii) seeking "priority review" of the Company's new drug application ("NDA") for EDSIVO.

9. Further, during the Relevant Period, the Director Defendants (defined herein) negligently issued a materially false and misleading proxy statement urging stockholders to reelect certain of the Individual Defendants under false pretenses.

10. As a direct and proximate result of the Individual Defendants' breaches of fiduciary duties and other misconduct, Acer has sustained damages as described below.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 14(a) of the Exchange Act (15 U.S.C. § 78n), and SEC Rule 14a-9 (17 C.F.R. § 240.14a-9) promulgated thereunder.

12. Plaintiff's claims also raise a federal question pertaining to the claims made in the Securities Class Action based on violations of the Exchange Act.

13. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

14. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

15. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1401 because Acer is headquartered in this District. In addition, Defendants have conducted business in this District, and Defendants' actions have had an effect in this District.

PARTIES

16. Plaintiff is a current stockholder of Acer common stock. Plaintiff has continuously held Acer common stock since at least September 2017.

17. Acer is a Delaware corporation with its principal executive offices at One Gateway Center, Suite 351, 300 Washington Street, Newton, Massachusetts 02458. Acer's common stock trades on the Nasdaq Capital Market ("NasdaqCM") under the ticker symbol "ACER."

18. Defendant Jason Amello ("Amello") has served as a director of the Board since September 2017. Defendant Amello also served as a member of the Company's Audit Committee during the Relevant Period.

19. Defendant Steve Aselage ("Aselage") has served as a director of the Board since September 2017.

20. Defendant Hubert Birner ("Birner") served as a director of the Board between September 2017 and May 2019.

21. Defendant John M. Dunn ("Dunn") has served as a director of the Board since September 2017. Defendant Dunn also served as a member of the Company's Audit Committee during the Relevant Period.

22. Defendant Michelle Griffin ("Griffin") has served as a director of the Board since September 2017. Defendant Griffin also served as Chair of the Company's Audit Committee during the Relevant Period.

23. Defendant Luc Marengere ("Marengere") served as a director of the Board between September 2017 and May 2019.

24. Defendant Harry Palmin ("Palmin") has served as the Company's Chief Financial Officer since September 2017. Defendant Palmin is named as a defendant in the Securities Class Action.

25. Defendant Chris Schelling ("Schelling") has served as the Company's Chief Executive Officer ("CEO") and President and as a director of the Board since September 2017. Defendant Schelling is named as a defendant in the Securities Class Action.

26. Defendants Palmin and Schelling are sometimes referred to herein as the "Securities Class Action Defendants."

27. Defendants Amello, Aselage, Birner, Dunn, Griffin, Marengere, and Schelling are sometimes referred to herein as the "Director Defendants."

28. Defendants Amello, Dunn, and Griffin are sometimes referred to herein as the "Audit Committee Defendants."

29. Defendants Amello, Aselage, Birner, Dunn, Griffin, Marengere, Palmin, and Schelling are sometimes referred to herein as the "Individual Defendants."

DUTIES OF THE INDIVIDUAL DEFENDANTS

30. By reason of their positions as officers and/or directors of the Company, and because of their ability to control the corporate affairs and business of the Company, the Individual Defendants owed the Company and its stockholders fiduciary obligations of good faith, trust, loyalty, and due care, and were and are required to use their best efforts to control and manage the Company in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of the Company and its stockholders so as to benefit all stockholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to the Company and its stockholders the fiduciary duty to exercise good faith and diligence in the administration of the Company's affairs and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

31. The Individual Defendants, because of their positions of control and authority as directors and/or officers of the Company, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

32. In addition, as officers and/or directors of a publicly-held company, the Individual Defendants have a duty to promptly disseminate accurate and truthful information with regard to the Company's operations, performance, management, projections, and forecasts so that the market price of the Company's stock will be based on truthful and accurate information.

33. To discharge their duties, the officers and directors of Acer were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls

of the Company. By virtue of such duties, the officers and directors of Acer were required to, among other things:

a. ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;

b. conduct the Company's affairs in a lawful, efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

c. properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's financial results and prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's financial reporting would be true and accurate at all times;

d. remain informed as to how the Company conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with federal and state securities laws; and

e. ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable federal, state, and local laws, rules and regulations.

34. Each of the Individual Defendants, as an executive officer and/or director, owed to the Company and to its stockholders the fiduciary duties of loyalty, good faith, and candor in the management and administration of the Company's affairs, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of the Company, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its stockholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

35. According to the Company's Corporate Governance Guidelines, the Director Defendants are required to "exercise its powers in accordance with its fiduciary duties to the

Company and in a manner it reasonably believes to be in the best interests of the Company and its stockholders." Further, the Corporate Governance Guidelines state that the Board must "oversee senior management in the competent and ethical operation of the Company."

36. The Company also maintains a Code of Business Conduct and Ethics (the "Code"). The Code sets forth legal and ethical standards of conduct for directors, officers, employees, and consultants of Acer and its subsidiaries.

37. According to the Code, the employees and directors of Acer are responsible for helping Acer maintain its good reputation and the trust and confidence of its stockholders, its employees, the public, and those with whom Acer does business.

38. Pursuant to the Code:

> **A. Honest and Candid Conduct**
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> Representatives are expected to act and perform their duties ethically and honestly with the utmost integrity. Honest conduct is considered to be conduct that is free from fraud or deception. Ethical conduct is considered to be conduct conforming to accepted professional standards of conduct. Ethical conduct includes the ethical handling of actual or apparent conflicts of interest between personal and professional relationships as discussed below.
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> **B. Conflicts of Interest**
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> A conflict of interest exists when an individual's private interest interferes or appears to interfere with the interests of the Company. A conflict of interest can arise when a Representative takes actions or has interests that may make it difficult to perform his or her Company work objectively and effectively. For example, a conflict of interest would arise if a Representative, or a member of his or her family, receives improper personal benefits as a result of his or her position in the Company. While it is not possible to describe every situation in which a conflict of interest may arise, Representatives must never use or attempt to use their position with the Company to obtain improper personal benefits
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> **C. Accuracy of Financial Reports and Other Public Communications**
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> The Company, as a public company, is subject to various securities laws, regulations and reporting obligations. Both federal law and our policies require the disclosure of accurate and complete information regarding the Company's business, financial condition and results of operations which may be filed with, or

submitted to, the SEC and other regulators or disseminated publicly. Inaccurate, incomplete or untimely reporting will not be tolerated and can severely damage the Company and result in legal liability.

Senior Financial Officers are responsible for ensuring that the disclosure in the Company's periodic reports is full, fair, accurate, timely and understandable. In doing so, Senior Financial Officers shall take such action as is reasonably appropriate to (i) establish and comply with disclosure controls and procedures and accounting and financial controls that are designed to ensure that material information relating to the Company is made known to them, (ii) confirm that the Company's periodic reports comply with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and (iii) ensure that information contained in the Company's periodic reports fairly presents in all material respects the financial condition and results of operations of the Company.

D. Compliance with Laws and Regulations

It is the Company's policy to comply with all applicable laws, rules, and regulations. It is the personal responsibility of each Representative to adhere to the standards and restrictions imposed by those laws, rules, and regulations. In performing his or her duties, each Representative will endeavor to comply, and take appropriate action within his or her areas of responsibility to cause the Company to comply, with applicable governmental laws, rules, and regulations.

39. In addition, the Company's Audit Committee is specifically tasked with the Board's oversight responsibilities. The conduct of the Audit Committee is governed by the Audit Committee Charter (the "Charter").

40. Pursuant to the Charter:

The purposes of the [Audit] Committee [the "Committee"] are to assist the Board in its oversight of:

1. the integrity of the Company's financial statements, financial reporting process, and systems of internal controls related to finance, accounting, legal and regulatory compliance; and

2. the independent auditors' qualifications, independence and performance.

The function of the Committee is oversight. The management of the Company is responsible for the preparation, presentation, and integrity of the Company's financial statements. Management is responsible for maintaining appropriate accounting and financial reporting principles and policies and internal controls and procedures that provide for compliance with accounting standards and applicable laws and regulations. The independent auditors are responsible for planning and

carrying out a proper audit of the Company's annual financial statements, reviews of the Company's quarterly financial statements prior to the filing of each quarterly report on Form 10-Q, and other procedures. In fulfilling their responsibilities hereunder, it is recognized that members of the Committee are not employees of the Company and are not, and do not represent themselves to be, performing the functions of auditors or accountants. As such, it is not the duty or responsibility of the Committee or its members to conduct "field work" or other types of auditing or accounting reviews or procedures or to set auditor independence standards.

* * *

To carry out its purposes, the Committee shall have the following duties and powers:

* * *

2. with respect to financial reporting principles and policies and internal controls and procedures:

(i) to advise management and the independent auditors that they are expected to provide to the Committee a timely analysis of significant financial reporting issues and practices;

(ii) to consider any reports or communications (and management's responses thereto) submitted to the Committee by the independent auditors, including reports and communications related to:

- deficiencies noted in the audit in the design or operation of internal controls;
- consideration of fraud in a financial statement audit;
- detection of illegal acts;
- any restriction on audit scope;
- significant accounting policies;
- management judgments and accounting estimates;
- any accounting adjustments arising from the audit that were noted or proposed by the auditors but were passed (as immaterial or otherwise);
- disagreements with management;
- difficulties encountered with management in performing the audit;
- the independent auditors' judgments about the quality of the entity's accounting principles; and

- reviews of interim financial information conducted by the independent auditors;

(iii) to meet with management and the independent auditors:

- to review and discuss the annual audited financial statements and quarterly financial statements, including the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations";

- to discuss any significant matters arising from any audit, including any audit problems or difficulties, whether raised by management or the independent auditors, relating to the Company's financial statements;

- to discuss any difficulties the independent auditors encountered in the course of the audit, including any restrictions on their activities or access to requested information and any significant disagreements with management;

- to review the form of opinion the independent auditors propose to render to the Board and stockholders; and

- to discuss, as appropriate: (a) any major issues regarding accounting principles and financial statement presentations, including any significant changes in the Company's selection or application of accounting principles, and major issues as to the adequacy of the Company's disclosure controls and procedures and internal control over financial reporting, and any special audit steps adopted in light of material control deficiencies; (b) analyses prepared by management and/or the independent auditors setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of alternative GAAP methods on the financial statements; and (c) the effect of regulatory and accounting initiatives, as well as off-balance sheet structures, on the financial statements of the Company;

(iv) to discuss with management the Company's major financial risk exposures and the steps management has taken to monitor and control such exposures, including the Company's policies with respect to financial risk assessment and financial risk management;

(v) to inquire of and review any disclosures made to the Committee by the Company's chief executive officer and chief financial officer (or persons performing such functions) during their certification process for the Company's Form 10-K and Forms 10-Q as to the existence of any significant deficiencies or material weaknesses in the design or operation of internal controls that could adversely affect the Company's ability to record, process, summarize and report financial data, and any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls;

(vi) to discuss with the Company's general counsel (or person or entity performing such function) any significant legal, compliance or regulatory matters that may have a material effect on the financial statements or the Company's business, financial statements or compliance policies, including material notices to or inquiries received from governmental agencies;

(vii) to discuss and review the type and presentation of information to be included in earnings press releases;

(viii) to establish procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters, and for the confidential, anonymous submission by Company employees of concerns regarding questionable accounting or auditing matters; and

(ix) to review and approve where appropriate any proposed "related person transactions" which may be required to be disclosed by the Company (pursuant to Item 404 of Regulation S-K), based on all relevant facts and circumstances reasonably available to the Committee (including, but not limited to: the nature of the related person's interest in the transaction; the material terms of the transaction, including, without limitation, the amount and type of transaction; the importance of the transaction to the related person; the importance of the transaction to the Company; whether the transaction would impair the judgment of a director or executive officer to act in the best interest of the Company; and any other matters the Committee deems appropriate), where approval is given by the Committee only for those transactions it determines are fair to and in the best interests of the Company, taking into account all factors deemed relevant by the Committee;

3. with respect to reporting and recommendations,

(i) to recommend to the Board, based on its review and discussions with management and the independent auditors, whether the Company's audited financial statements should be included in the Company's annual report on Form 10-K;

(ii) to prepare any report or other disclosures, including any recommendation of the Committee, required by the rules of the SEC to be included in the Company's annual proxy statement;

(iii) to review and reassess the adequacy of this Charter at least annually and recommend any changes to the full Board;

(iv) to prepare and review with the Board an annual performance evaluation of the Committee, which evaluation shall compare the performance of the Committee with the requirements of this Charter;

(v) to report its activities to the full Board on a regular basis and to make such recommendations with respect to the above and other matters as the Committee may deem necessary or appropriate;

(vi) in the case of matters concerning accounting, internal controls or auditing, to monitor compliance with the Company's Code of Ethics and when appropriate, impose and enforce appropriate disciplinary measures for violations of the Code; and

(vii) to review any proposed waiver of the Code and make a recommendation to the Board with respect to the disposition of any proposed waiver.

41. In violation of the Audit Committee Charter, and their general duties as members of the Audit Committee, the Audit Committee Defendants conducted little, if any, oversight of the Company's internal controls or the Company's compliance with legal and regulatory requirements resulting in materially false and misleading statements regarding the Company's business, operational, and compliance policies, and consciously disregarded their duties to monitor such controls over reporting. The Audit Committee Defendants' complete failure to perform their duties in good faith resulted in false statements to the SEC, the investing public, and the Company's stockholders.

42. In addition, as executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the Nasdaq, the Individual Defendants had a duty not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, including false and misleading information about acquisitions, so that the market price of the Company's common stock would be based upon truthful and accurate information. Accordingly, the Individual Defendants breached their fiduciary duties by knowingly or recklessly causing Acer to make false and misleading statements of

material fact about the Company's financials and about Acer's maintenance of adequate internal controls.

43. Each of the Individual Defendants further owed to Acer and its stockholders the duty of loyalty requiring that each favor Acer's interest and that of its stockholders over their own while conducting the affairs of the Company and refrain from using their position, influence, or knowledge of the affairs of the Company to gain personal advantage.

SUBSTANTIVE ALLEGATIONS

BACKGROUND

44. Acer, a pharmaceutical company based in Newton, Massachusetts, was founded in 2013 by defendant Schelling. On September 19, 2017, the Company, private at the time, completed a reverse merger with Opexa Therapeutics, Inc. ("Opexa"), a publicly traded pharmaceutical corporation trading under the symbol "OPXA."

45. Upon closing of the reverse merger, the directors and the sole executive officer of Opexa resigned from their positions with Opexa, while the surviving, combined company continued its operations under the leadership of Acer's executive management team, including defendant Schelling. Also, as a result of the reverse merger, the combined company changed the ticker from "OPXA" to "ACER" and began trading publicly on NasdaqCM.

46. As of December 31, 2018, Acer had twenty-three full-time employees. The Company also employed a number of consultants and independent contractors.

47. During the Relevant Period, the Company had three clinical-stage candidates: (1) EDSIVO, (2) ACER-001, and (3) osanetant. The Company had not generated any revenue from commercial sales of any of the three candidates. Thus, the Company's future depended on its "ability to generate these product candidates or other product candidates that we may develop, in-license or acquire in the future."

48. And, this ability to generate revenue depended on the Company obtaining FDA approval. Indeed, the Individual Defendants, in numerous public statements, admitted that "Our business is substantially dependent on our ability to complete the development of, obtaining marketing approval for, and successfully commercialize our product candidates in a timely manner. We cannot commercialize our product candidates in the United States without first obtaining approval from the FDA to market each product candidate." The Individual Defendants also admitted that "our business will be substantially harmed . . . if we are ultimately unable to obtain marketing approval for our product candidate."

49. The Company designated most of its resources to clinical development of its product candidates. Since its founding, the Company expended more than $28 million in research and development ("R&D") through the end of 2018. Of the R&D expenses, approximately $23.6 million was spent in developing EDSIVO, indicating the importance the Company placed on this drug.

50. The Company has been developing EDSIVO to treat vEDS by repurposing celiprolol. vEDS is a rare and severe genetic connective tissue disorder caused by mutations in the collagen type III alpha I chain gene that affects thousands of people in the United States. Patients with vEDS have abnormally fragile blood vessels, which may result in aneurysms, abnormal connections between blood vessels, arterial dissections, and spontaneous vascular ruptures, all of which can be fatal. Patients with vEDS are recommended to avoid intense physical activity, including strenuous sports and scuba diving. Complications resulting from vEDS are severe and often require immediate hospitalization, intensive care, or surgery.

51. Although celiprolol has not been approved for treating vEDS in the United States, it has been approved for the treatment of hypertension in the European Union for over 30 years and has been widely used to treat vEDS in France.

52. On December 13, 2016, the Company announced that it had signed an agreement with Assistance Publique—Hôpitaux de Paris, Hôpital Européen Georges Pompidou ("AP-HP"), which is based in Paris, France. The agreement would grant the Company exclusive rights to access and use data from a randomized, controlled clinical study of celiprolol.

53. In 2004, AP-HP researchers published data on their vEDS patients, observing that an abnormally low intima-media thickness generates a higher wall stress than in control subjects at the site of an electric artery, which increased the risk of arterial dissection and rupture.

54. Based on these findings, AP-HP sought to figure out how to use celiprolol for vEDS patients to lower risk of arterial dissection and rupture and began the Ong Trial, a multicenter, prospective, randomized, open trial with blinded evaluation of clinical events, which was funded by the French Ministry of Health. Professor Pierre Boutouyrie was appointed as the principal investigator for the Ong Trial.

55. 53 patients participated in the Ong Trial, who were randomly split up at eight centers in France and one center in Belgium. The trial's primary endpoint was a composite of cardiac or arterial events, such as rupture or dissection, during follow-up. The trial's secondary endpoints were gastrointestinal or uterine rupture.

56. On October 30, 2010, AP-HP published results from the Ong Trial in *The Lancet*, a weekly, peer-reviewed medical journal.

57. According to the Individual Defendants, the Ong Trial ended early "after a consensus decision of the safety monitoring board, the methodologist of AP-HP, and the principal

investigator because significant differences were recorded between the treatment group and the control group after 64 months." The Individual Defendants also touted, "[W]ith celiprolol the risk of having a cardiac or arterial event was reduced by 64% compared to [the] control [group]."

58. In reality, the Ong Trial suffered from fatal flaws. During the trial, researchers learned that more than one-third of the participants did not have a COL3A1 gene mutation, which is the cause of vEDS. Additionally, the participants without the COL3A1 gene mutation were not evenly distributed between the control group and the test group. While the treatment group consisted of 12 participants who did not have a COL3A1 mutation and 13 participants who did, the control group consisted of 8 participants who did not have a COL3A1 mutation and 20 participants who did, creating a severe imbalance between the treatment group and the control group.

59. The Ong Trial bias can be quantified from the percentages of the study's participants who did not have the genetic mutation, which was 48% (12 out of 25) for the treatment group and 28.6% (8 out of 28) for the control group. From the outset, the treatment group had a 19.4% head start towards event-free survival, which is highly material and equates to a 5-event advantage for the treatment group. Given that an 8-event advantage reaches statistical significance, any scenario among the 13 treatment cases and the 20 control cases with the mutation where there are just three fewer events in the mutation present treatment group will result in a statistically significant event-free survival advantage. This is a red flag that the FDA would immediately have recognized as bias upon reviewing the mutation data.

60. Further, with respect to the remaining 33 cases (13+20) with mutations, there was less than 80% power to detect a 50% difference (*i.e.*, 25% vs. 75%), rendering the Ong Trial subgroup very underpowered. In other words, after excluding the ineligible cases, the study lacked

an adequate sample size to test for a meaningful difference between the two groups and, therefore, was unlikely to yield any conclusive results. This is another red flag that the FDA would have recognized as soon as the agency learned about the 20 (12+8) ineligible cases.

61. Such severe imbalance between the treatment group and the control group would likely cause the FDA to be reluctant in approving celiprolol and, in turn, EDVISO, because the severe imbalance indicates that the study was not "adequate and well-controlled."

62. In addition to the severe imbalance problem, the Ong Trial also suffered from bias issues that would cause the FDA to be reluctant in approving celiprolol. The FDA has a strong preference for prospective studies, which have fewer potential sources of bias and confounding than retrospective studies. The Ong Trial's statistical significance was not controlled and was based on retrospective analysis of historical data, which the FDA would recognize as another source of bias upon learning of the Company's use of the Ong Trial data as the main source of the Company's NDA.

63. Despite having knowledge of the severe bias issues in the Ong Trial, which significantly lowered the chance of FDA approval for EDSIVO, the Individual Defendants touted the purported positive results of the Ong Trial while omitting biases and underpowering flaws of the trial.

64. From when the Company acquired the Ong Trial data, the Individual Defendants made clear that the Ong Trial data would be the main source for the upcoming NDA for EDSIVO. For example, on December 13, 2016, the Individual Defendants caused the Company to issue a press release which stated, "This pivotal clinical data from AP-HP will represent a critical element of the clinical module in our NDA [New Drug Application], which we are diligently building along with manufacturing, non-clinical and other components of the regulatory package."

65. The Individual Defendants continued to tout the Ong Trial data. On September 25, 2017, the Individual Defendants caused the Company to issue a press release announcing that the Company had obtained "positive results" from the Company's own "retrospective source verified analysis of the [Ong T]rial data, including the primary and secondary endpoints."

66. The Individual Defendants continued, stating that "The previously completed European study, published on October 30, 2010, in *The Lancet*, was stopped early having achieved statistical significance in its primary endpoints." According to the September 25, 2017 press release, "Acer will use this pivotal clinical data to support a New Drug Application (NDA) regulatory filing in the U.S. in the first half of 2018."

THE FDA'S REVIEW PROCESS FOR ACER'S NDA FOR EDSIVO

67. The FDA approves a new drug for sale and marketing in the United States. through an NDA process. As stated on the FDA's website, "The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions: [a] whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks; [b] whether the drug's proposed labeling (package insert) is appropriate, and what it should contain; and [c] whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity."

68. Further, the FDA describes that the NDA "is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged."

69. The Individual Defendants likewise described the NDA process in public statements:

> The FDA is required to conduct a preliminary review of an NDA within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may accept the NDA for filing, potentially refuse to file the NDA due to deficiencies but work with the applicant to rectify the deficiencies (in which case the NDA is filed upon resolution of the deficiencies) or refuse to file the NDA. The FDA must notify the applicant of a refusal to file a decision within 60 days after the original receipt date of the application. . . . Once an NDA is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act ("PDUFA") and the FDA's commitments under the current PDUFA Reauthorization Act, the FDA has a goal of reviewing and acting on 90% of standard non-priority NDA applications within ten months from the filing date of the NDA.

70. Through the PDUFA, the FDA enables applicants that have submitted NDAs meeting certain criteria to receive a decision within six months through its "priority review" designation, instead of the ten-month period under the FDA's standard review. According to the FDA:

> A Priority Review designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.
>
> Significant improvement may be demonstrated by the following examples:
>
> - evidence of increased effectiveness in treatment, prevention, or diagnosis of condition;
> - elimination or substantial reduction of a treatment-limiting drug reaction;
> - documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes; or
> - evidence of safety and effectiveness in a new subpopulation.
>
> FDA decides on the review designation for every application. However, an applicant may expressly request priority review as described in the Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. It does not affect the length of the clinical trial period. FDA informs the applicant of a Priority Review designation within 60 days of the receipt of the original BLA, NDA, or efficacy supplement. Designation of a drug as "Priority" does not alter the scientific/medical standard for approval or the quality of evidence necessary.

71. After conducting its review centered on the drug candidate's safety and efficacy, the FDA then issues its decision by letter either approving the NDA or rejecting or denying the

NDA. If the FDA rejects or denies the NDA, it issues a Complete Response Letter ("CRL"), which must, under 21 C.F.R. § 314.110(a)(1), contain "all of the specific deficiencies that the agency has identified":

> The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for its intended use and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation in response to specific questions raised by the FDA, which may include whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.
>
> * * *
>
> After the FDA evaluates the NDA and conducts its inspections, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug subject to specific prescribing information for specific indications and, if applicable, specific post-approval requirements. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. After receiving a Complete Response Letter, the applicant must decide within twelve months (subject to extension), if it wants to resubmit the NDA addressing the deficiencies identified by the FDA in the Complete Response Letter, withdraw the NDA, or request an opportunity for a hearing to challenge the FDA's determination. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret data.

72. During the Relevant Period, the Individual Defendants represented to the public that the Company was working closely with the FDA in preparing Acer's NDA for the agency's review and fostered the impression that in working with representatives from the FDA that the Company would be able to resolve any gaps existing between the data package the Company

intended to include in the NDA and the FDA's requirements, which would substantially reduce the risk that its NDA for EDSIVO would receive a CRL.

73. Early in the Relevant Period, the Individual Defendants reported that the Company and the FDA had reached an agreement that the Company would not need to conduct any clinical studies beyond the already-completed Ong Trial. For example, in a Preliminary Prospectus Supplement filed with the SEC on December 11, 2017, and in a Prospectus Supplement filed with the SEC on December 12, 2017, the Individual Defendants reported that at a September 2015 meeting at which Acer "met with the FDA to discuss the existing clinical data for EDSIVO," "***the FDA agreed that additional clinical development is not needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS" (emphasis added). This was material information because the Individual Defendants "anticipate[d] [that] the use of third-party data will minimize the amount of original data we would be required to generate and shorten the time needed for preparation, submission, and review of the marketing applications."

74. In fact, the Individual Defendants' representation that the Company had an agreement with the FDA was not true. Later in the Relevant Period, the Individual Defendants began backtracking on the supposed agreement with the FDA. In a Form 10-K filed with the SEC on March 7, 2018, the Individual Defendants described the supposed agreement with the FDA: "In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO. ***At that meeting, the FDA agreed that an additional clinical trial is not likely needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS" (emphasis added). The Individual Defendants added: "Furthermore, ***the FDA provided us with additional guidance*** on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing."

75. Similarly, in prospectus supplements filed with the SEC to raise capital from investors, the Individual Defendants stated: "In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO. ***At that meeting, the FDA agreed that an additional clinical trial is not likely needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS" (emphasis added). Defendants also added: "Furthermore, ***the FDA provided us with additional guidance*** on the expected presentation of the existing clinical data for EDSIVO to support the NDA filing." (emphasis added).

76. On the contrary, based on the Individual Defendants' later admission that "[t]he CRL states that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS," the FDA had previously communicated to the Company that the agency did not consider the Ong Trial an "adequate and well-controlled trial" as a result of the imbalance between the experimental and control arms of the Ong Trial. Indeed, the FDA would not lead the Individual Defendants to believe that the agency considered the Ong Trial an "adequate and well-controlled trial," and then later deny the Company's NDA on the ground that the Ong Trial did not constitute an "adequate and well-controlled trial."

77. In the months leading up to Acer's submission of its NDA for EDSIVO, the Individual Defendants continued to suggest that there were no serious impediments to FDA approval for EDSIVO.

78. On March 7, 2018, the Individual Defendants caused the Company to file a Form 10-K for the fiscal year 2017, which stated that "[i]n September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO." The Individual Defendants also represented that "[i]n May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing

data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. . . . [T]he FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO to support the NDA filing."

79. As to the timing of the FDA process, the Individual Defendants stated that they "plan[ned] to have a pre-NDA meeting, which may consist of one or more consults, with the FDA in the second quarter of 2018," and that they expected "to submit the 505(b)(2) NDA for EDSIVO for the treatment of vEDS at the end of the first half of 2018."

80. On March 7, 2018, the Individual Defendants caused the Company to issue a press release, which stated that they "plan to discuss these key data," consisting of the "positive results" obtained from the Company's own "retrospective source-verified analysis of the trial data, including the primary and secondary endpoints, confirm[ing] the data from a previously published randomized controlled clinical study of celiprolol . . . during a pre-NDA meeting with the FDA in the second quarter of 2018."

81. On August 13, 2018, the Individual Defendants caused the Company to issue a press release announcing the Company's financial and operational results for the second quarter of fiscal year 2018. In the press release, the Individual Defendants stated that they had "held a Type C clinical meeting and a Type B (pre-NDA) meeting with the FDA in June 2018," and that they had "presented celiprolol vEDS Patient Registry data to the FDA at the Type C meeting." The Individual Defendants also represented that the manuscript of the patient registry data was then "currently under peer review," and "if published, it will be included in support of NDA but is not rate-limiting to submission of NDA." The Individual Defendants also stated that they were "targeting NDA submission to the FDA for EDSIVO for the treatment of vEDS in early fourth quarter of 2018."

82. On December 26, 2018, the Individual Defendants caused the Company to issue a press release announcing that the FDA had accepted for review the Company's NDA for EDSIVO. In the press release, the Individual Defendants noted that "[t]he FDA also granted a priority review of the NDA and assigned a [PDUFA] target action date of June 25, 2019. Priority review is a designation granted by the FDA to accelerate the review process for drugs that offer a significant improvement in treatment or provide treatment where no satisfactory alternative therapy exists."

83. On April 16, 2019, the Individual Defendants caused the Company to issue a press release announcing the publication of "long-term data from a cohort of COL3A1-positive vEDS patients in the *Journal of the American College of Cardiology*" (the "Long-Term Observational Study"). In the press release, the Individual Defendants stated that the Long-Term Observational Study, titled "Vascular Ehlers-Danlos Syndrome: Long-Term Observational Study" and authored by Michael Frank, MD, Xavier Jeunemaitre, MD, PhD and Pierre Boutouyrie, MD, PhD, et al., "describes outcomes in 144 COL3A1-positive vEDS patients clinically monitored and treated at the French National Referral Center for Rare Vascular Diseases (Paris, France) between the years 2000 and 2017." The Individual Defendants quoted Dr. Michael Frank, a clinical investigator from the Paris Group and one of the co-authors of the Long-Term Observational Study, as stating, "The higher overall survival in patients treated with celiprolol in this long-term study in COL3A1-positive vEDS patients appears to correlate with the significant event-free survival advantage that was reported in the [Ong Trial] of celiprolol treatment in vEDS patients."

84. Despite the Individual Defendants' selective quotation of the Long-Term Observational study, the researchers of the Long-Term Observational Study themselves stated, "It is difficult to formally assess this beneficial effect (the benefit of celiprolol on survival) in the absence of a placebo-controlled prospective trial, because other confounders might have

influenced this observation." As Dr. Julie De Backer and Dr. Tine De Backer, vEDS researchers not affiliated with the Long-Term Observational Study, stated:

> Whether the systematic treatment with celiprolol has an additional genuine pharmacological beneficial effect or helps ensure better follow up cannot be answered with this study. The only way to determine if it is celiprolol contributing to the better outcome is to conduct a randomized prospective trial comparing celiprolol to another beta-blocker in patients with molecularly confirmed vEDS.

85. Beginning on June 25, 2019, the Individual Defendants began disclosing the truth about the FDA review process. On June 25, 2019, the Individual Defendants announced that the FDA had rejected the Company's NDA for EDSIVO, pointing out the need for an adequate and well-controlled trial" evaluating EDSIVO.

86. Defendants issued a press release (the "June 25, 2019 Press Release") disclosing that the FDA had rejected Acer's NDA for EDSIVO. Although Defendants did not make the CRL available to the public, the June 25, 2019 Press Release reported that the CRL had cited the need for an "adequate and well-controlled trial" evaluating EDSIVO's effectiveness in reducing the risk of clinical events in patients with vEDS. Nevertheless, the Individual Defendants represented to the public that they "expect[ed] to respond to the FDA in the third quarter of [2019]." Interestingly, the press release had no mention of a supposed agreement with the FDA.

87. On July 5, 2019, the Individual Defendants issued a press release announcing that, in light of the FDA's issuance of the CRL to Acer regarding its NDA for EDSIVO, the Company was undergoing a "corporate restructuring," as a result of which "Acer's headcount has been reduced from 48 to 19 employees and pre-commercial activities of EDSIVO (celiprolol) have been halted. The restructuring is expected to provide the resources needed for Acer to conduct its planned business operations through 2020." The Individual Defendants also noted that they "intend to continue our dialogue with the FDA to fully understand its response and work toward our goal of approval of EDSIVO." The Individual Defendants added that "[i]n light of the CRL it

was necessary to reduce our expenses, extend our cash runway, and focus our resources on a potential path forward for EDSIVO as well as continued development of our other pipeline opportunities."

THE INDIVIDUAL DEFENDANTS CAUSE THE COMPANY TO ISSUE MATERIALLY FALSE AND MISLEADING STATEMENTS

88. During the Relevant Period, the Individual Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, the Individual Defendants failed to disclose to investors that: (i) the Ong Trial data were insufficient to support FDA approval based on the imbalance between the study's experimental and control arms, and the severe bias and underpowering of the study; (ii) the significant limitation of the Long-Term Observational Study in that it could not answer "whether the systematic treatment with celiprolol has an additional genuine pharmacological beneficial event; and (iii) communications from the FDA that the Ong Trial data were flawed and the limited value of the Long-Term Observational Study.

89. On September 25, 2017, the Individual Defendants caused the Company to issue a press release titled "*Acer Therapeutics Reports Positive Results From Pivotal Clinical Trial of EDSIVO™ (celiprolol) for Treatment of Vascular Ehlers-Danlos Syndrome*," which stated:

> Cambridge, MA – Acer Therapeutics Inc., (Nasdaq: ACER), a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and ultra-rare diseases with critical unmet medical need, today announced ***positive results from the pivotal clinical trial of EDSIVO™ (celiprolol)*** for the treatment of vascular Ehlers-Danlos Syndrome (vEDS). ***Acer's retrospective source verified analysis of the trial data, including the primary and secondary endpoints, confirmed the data from a previously published randomized controlled clinical study of celiprolol(1). Acer will use this pivotal clinical data to support a New Drug Application (NDA) regulatory filing in the U.S. in the first half of 2018.*** Ehlers-Danlos Syndrome (EDS) is a group of hereditary disorders of connective tissue. vEDS is the most severe subtype where patients suffer from life threatening arterial dissections and ruptures, as well as intestinal and uterine ruptures. There are currently no FDA approved

> therapies for vEDS(2). "We have studied celiprolol for nearly two decades in vEDS patients and this is the only drug to ever demonstrate a clinical benefit in this difficult to treat patient population in a randomized, controlled clinical study," said Pierre Boutouyrie M.D., Ph.D., co-director of the clinical pharmacology service at the Georges-Pompidou European Hospital, Greater Paris University Hospitals (AP-HP) and Principal Investigator for the published celiprolol study. "Having established celiprolol as the standard of care in France for vEDS patients, we are excited to collaborate with Acer to help bring celiprolol to U.S. patients who are suffering from this devastating, life-threatening disease." ***The previously completed European study, published on October 30, 2010, in The Lancet, was stopped early having achieved statistical significance in its primary endpoints, with arterial dissection or rupture affecting 5 (20%) celiprolol patients and 14 (50%) subjects in the non-treated control group (hazard ratio [HR] 0.36; p-value 0.04).*** The combined primary and secondary endpoints of intestinal or uterine rupture affected 6 (24%) celiprolol patients and 17 (61%) subjects in the non-treated control group (HR 0.31; p-value 0.01). The study was conducted in 53 patients, who were randomly assigned either a twice daily treatment of celiprolol or no treatment. Mean duration of follow-up was 47 months prior to trial halt. "We are committed to bringing EDSIVO™ to vEDS patients who currently do not have access to this treatment," said Robert D. Steiner, M.D., Chief Medical Officer of Acer. ***"Our confirmation of the published celiprolol clinical data with an Acer-sponsored retrospective source verified analysis of the trial data represents a critical element of the clinical module in our NDA,*** which we are diligently building, along with current manufacturing, non-clinical and other components of the regulatory package." "We continue to successfully rapidly advance our lead product candidate, EDSIVO™, a potential life-saving therapy for patients with vEDS, towards an NDA filing, which we expect to accomplish in the first half of 2018," said Chris Schelling, CEO and Founder of Acer. ***"In addition to source verifying a definitive Event-Free Survival endpoint from a previously completed robust clinical study, modernizing manufacturing and assembling other components of the regulatory package, we are executing on a number of key medical affairs focused initiatives for vEDS patients.*** Specifically, we are setting up Centers of Excellence to optimize patient care, and intend to develop a prospective vEDS Patient Registry and provide integrated care support programs."

(emphases added).

90. On November 13, 2017, the Individual Defendants caused the Company to issue a press release announcing the Company's financial and operational results for the third quarter of fiscal year 2017. In the press release, defendant Schelling was quoted:

> We became a public Nasdaq-listed company, closed a concurrent financing and ***announced positive results from our pivotal clinical trial of EDSIVO™, each a critical step in bringing us closer to our goal of becoming a leading pharmaceutical company that acquires, develops and commercializes therapies for the treatment of patients with serious rare and ultra-rare diseases with critical unmet medical need . . . . We continue to successfully advance our lead product candidate, EDSIVO™, a potential life-saving therapy for patients with vEDS.*** We believe that our current cash position will allow us to advance EDSIVO™ through NDA submission with the FDA in the first half of 2018. As a public company, we look forward to advancing and expanding our pipeline with the goal of bringing multiple products to patients over the next several years.

(emphases added).

91. On December 11, 2017, the Individual Defendants caused the Company to file a Form 424B3 preliminary prospectus supplement (the "December 11, 2017 Preliminary Prospectus Supplement") with the SEC in connection with its secondary public offering of common stock. The next day, on December 12, 2017, the Individual Defendants caused the Company to file a substantially similar Form 424B3 prospectus supplement (the "December 12, 2017 Prospectus Supplement," and together with the December 11, 2017 Preliminary Prospectus, the "December 2017 Offering Documents") with the SEC. In the December 2017 Offering Documents, the Individual Defendants stated:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS.*** In addition, the FDA advised us that no significant additional work would be required for the chemistry, manufacturing and controls, nonclinical or pharmacology sections of the NDA. The FDA also indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ would qualify for priority review, which provides an expedited six-month review cycle, instead of the traditional ten-month cycle, for a drug that treats a serious condition and demonstrates the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is submitted. We expect to submit to the FDA the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS in the first half of 2018.

(emphasis added).

92. As a result of the December 2017 Offering Documents, the Company raised approximately $12.56 million from investors.

93. On March 7, 2018, the Individual Defendants caused the Company to issue a press release announcing the Company's financial and operational results for the fourth quarter of fiscal 2017 and 2017 annually. In the press release, the Individual Defendants touted the "positive results from the pivotal clinical trial of EDSIVO™ (celiprolol) for the treatment of vEDS." The Individual Defendants further stated that the Company's "retrospective source-verified analysis of the trial data, including the primary and secondary endpoints, confirmed the data from a previously published randomized controlled clinical study of celiprolol. We plan to discuss these key data during a pre-NDA meeting with the FDA in the second quarter of 2018."

94. Additionally, on the same day, the Individual Defendants caused the Company to file a Form 10-K (the "2017 10-K") with the SEC, which was signed by the Individual Defendants. The 2018 10-K stated:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS.*** The FDA indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ is likely to qualify for priority review. Priority review provides an expedited six-month review cycle after acceptance of the NDA for filing, instead of the traditional ten-month review cycle, for drugs that treat a serious condition and demonstrate the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is accepted for filing.
>
> In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. ***Furthermore, the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing.***

(emphases added).

95. On July 31, 2018, the Individual Defendants caused the Company to file a Form 424B3 preliminary prospectus supplement (the "July 31, 2018 Prospectus Supplement") with the SEC in connection with the SPO. The next day, on August 1, 2018, the Individual Defendants caused the Company to file a substantially similar Form 424B2 prospectus supplement (the "August 1, 2018 Prospectus Supplement," and together with the July 31, 2018 Preliminary Prospectus, the "August 2018 Offering Documents") with the SEC. In the August 2018 Offering Documents, the Individual Defendants stated:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS.*** The FDA indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ is likely to qualify for priority review. Priority review provides an expedited six-month review cycle after acceptance of the NDA for filing, instead of the traditional ten-month review cycle, for drugs that treat a serious condition and demonstrate the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is accepted for filing.
>
> In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. ***Furthermore, the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing.***

(emphases added).

96. As a result of the August 2018 Offering Documents, the Company raised approximately $46 million from investors.

97. On April 16, 2019, the Individual Defendants caused the Company to issue a press release discussing the Long-Term Observational Study, which the Individual Defendants cited to buttress their claims regarding EDSIVO. The press release stated:

> The authors concluded that in this large, long-term cohort study, vEDS patients had a higher survival rate than expected relative to the known natural history of the disease and a lower annual occurrence of arterial complications, and that celiprolol use was potentially associated with these significant improvements in clinical outcomes.
>
> "The higher overall survival in patients treated with celiprolol in this long-term study in COL3A1-positive vEDS patients appears to correlate with the significant event-free survival advantage that was reported in the Ong, et al. study of celiprolol treatment in vEDS patients (2)," said Michael Frank, MD, clinical investigator from the Paris group and first author of the publication.
>
> "We are pleased to see this publication from the vEDS clinical investigator group in Paris which provides patients and physicians with a greater understanding of this chronic disease, including data suggesting a positive impact of celiprolol, which has a unique pharmacological profile," said William Andrews, MD, FACP, Chief Medical Officer of Acer.

98. The Individual Defendants continued to tout the Long-Term Observational Study the following month. On May 14, 2019, the Individual Defendants caused the Company to issue a press release, which touted that "in April 2019, we announced the publication of the Paris registry data in JACC that supplements the previously-reported safety and efficacy of celiprolol in vEDS patients with a confirmed type III collagen (COL3A1) mutation." In the press release, the Individual Defendants also stated that the Company, in the first quarter of fiscal year 2019:

> Announced the publication of long-term data from a cohort of COL3A1-positive vascular Ehlers-Danlos syndrome (vEDS) patients in the Journal of the American College of Cardiology (JACC). The published data includes up to 17 years of safety data in this population, and the survival curve analysis shows that those patients not treated with celiprolol had a significantly worse outcome than celiprolol-treated patients. The authors also observed a relative decrease in hospitalization rates for acute arterial events during the time period in which the majority of patients were on celiprolol, suggesting a positive effect of celiprolol on the incidence and/or severity of new arterial events.

99. The statements in paragraphs 89-98 were materially false and/or misleading because the Individual Defendants failed to disclose to investors that: (i) the Ong Trial data was insufficient to support FDA approval based on the imbalance between the study's experimental and control arms, and the severe bias and underpowering of the study; (ii) the significant limitation of the Long-Term Observational Study in that it could not answer "whether the systematic treatment with celiprolol has an additional genuine pharmacological beneficial event; and (iii) communications from the FDA that the Ong Trial data were flawed and the limited value of the Long-Term Observational Study.

THE TRUTH IS REVEALED

100. On June 25, 2019, the Company issued a press release, which revealed that the FDA had rejected the Company's NDA for EDSIVO. Specifically, the press release stated:

> Acer Therapeutics Inc. (Nasdaq: ACER), a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs, today announced it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for EDSIVO™ for the treatment of vascular Ehlers-Danlos syndrome (vEDS). The CRL states that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS. Acer plans to request a meeting to discuss the FDA's response.
>
> "We remain committed to working closely with the FDA to fully understand its response," said Chris Schelling, CEO and Founder of Acer. "We expect to respond to the FDA in the third quarter of this year."

101. Later that day, Reuters published an article reporting that the FDA declined to approve Acer's NDA for EDSIVO and noted how "[t]he small group size" of the Ong Trial had "raised questions among experts about the adequacy of the trial results."

102. As a result, the price of Acer common stock fell $15.16 per share, or 78.63%, to close at $4.12 per share on June 25, 2019.

THE DIRECTOR DEFENDANTS ISSUED A MATERIALLY FALSE AND MISLEADING PROXY STATEMENT DURING THE RELEVANT PERIOD.

103. In addition to the above false and misleading statements issued and/or caused to be issued by the Individual Defendants, the Director Defendants also caused the Company to issue a false and misleading proxy statement during the Relevant Period. The Director Defendants drafted, approved, reviewed, and/or signed a Form DEF14A before it was filed with the SEC and disseminated to Acer's stockholders on April 12, 2019 (the "2019 Proxy"). The Director Defendants negligently issued materially misleading statements in the 2019 Proxy. These proxy allegations are based solely on negligence, they are not based on any allegations of recklessness or knowing conduct by or on behalf of the Individual Defendants, and they do not allege and do not sound in fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to the proxy allegations and related claims.

104. The 2019 Proxy sought stockholder votes to, among other things, elect defendants Aselage, Amello, Dunn, Griffin, and Schelling for a one-year term.

105. In support of the Director Defendants' bid to reelect defendants Aselage, Amello, Dunn, Griffin, and Schelling, the Director Defendants highlighted their supposed oversight of the Company. In particular, the 2019 Proxy assured stockholders that the Board and its committees regularly assess and manage the risks that Acer faces, including legal and regulatory risks, financial controls, and risks associated with compensation programs and plans. The 2019 Proxy stated:

> **Risk Oversight**
>
> A fundamental part of risk management is not only understanding the risks a company faces and what steps management is taking to manage those risks, but also understanding what level of risk is appropriate for each company. Our Board is actively involved in oversight of risks that could affect Acer. The full Board has retained the responsibility for general oversight of risks, but the Audit Committee primarily oversees those risks that may directly or indirectly impact our financial

statements. The Board's role in the risk oversight process includes receiving reports from members of management and the Audit Committee on areas of material risk to Acer, including operational, financial, legal and regulatory, and strategic risks which enable it to better understand our risk identification, management and mitigation strategies.

* * *

AUDIT COMMITTEE REPORT

The Audit Committee of the Board of Directors currently consists of Ms. Griffin and Messrs. Amello and Dunn, all of whom are independent, non-employee directors.

The Audit Committee operates under a written charter adopted by the Board, which is evaluated annually. The Audit Committee selects, evaluates and, where deemed appropriate, replaces the Company's independent auditors. The Audit Committee also pre-approves all audit services, engagement fees and terms, and all permitted non-audit engagements, except for certain de minimis amounts.

Management is responsible for the Company's internal controls and the financial reporting process. The Company's independent auditors are responsible for performing an independent audit of Acer's consolidated financial statements in accordance with auditing standards generally accepted in the United States of America and issuing a report on Acer's consolidated financial statements. The Audit Committee's responsibility is to monitor and oversee these processes.

In this context, the Audit Committee has reviewed the Company's audited financial statements for fiscal 2018 and has met and held discussions with management and Wolf & Company, P.C., the Company's independent auditors for fiscal 2018. Management represented to the Audit Committee that the Company's consolidated financial statements for fiscal 2018 were prepared in accordance with accounting principles generally accepted in the United States of America, and the Audit Committee discussed the consolidated financial statements with the independent auditors. The Audit Committee also discussed with Wolf & Company, P.C. the matters required to be discussed by Auditing Standard No. 16, *Communications with Audit Committees*, as adopted by the Public Company Accounting Oversight Board (PCAOB).

Wolf & Company, P.C. also provided to the Audit Committee the written disclosures and the letter required by applicable requirements of the PCAOB regarding the independent auditors' communications with the Audit Committee concerning independence, and the Audit Committee discussed with Wolf & Company, P.C. the accounting firm's independence.

Based upon the Audit Committee's discussion with management and Wolf & Company, P.C., and the Audit Committee's review of the representation of management and the report of Wolf & Company, P.C. to the Audit Committee, the

> Audit Committee recommended to the Board of Directors that the audited consolidated financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed with the SEC.

106. The 2019 Proxy thus assured stockholders that both the Individual Defendants and the Board was involved with Acer's business strategy, actively monitored the Company's risks and exposures, following good corporate governance practices, and acting in an ethical and legal manner. In reality, the Director Defendants were utterly failing in their oversight duties by allowing the Company to operate with inadequate internal controls which resulted in the failure to disclose to investors that: (i) the Ong Trial data were insufficient to support FDA approval based on the imbalance between the study's experimental and control arms, and the severe bias and underpowering of the study; (ii) the significant limitation of the Long-Term Observational Study in that it could not answer "whether the systematic treatment with celiprolol has an additional genuine pharmacological beneficial event; and (iii) communications from the FDA that the Ong Trial data were flawed and the limited value of the Long-Term Observational Study.

107. As a result of these misleading statements, the Company's stockholders voted via an uninformed stockholder vote to reelect defendants Aselage, Amello, Dunn, Griffin, and Schelling.

DAMAGES TO THE COMPANY

108. As a result of the Individual Defendants' wrongful conduct, Acer disseminated false and misleading statements and omitted material information to make such statements not false and misleading when made. The improper statements have devastated Acer's credibility. Acer has been, and will continue to be, severely damaged and injured by the Individual Defendants' misconduct.

109. Furthermore, aside from ruining the Company's reputation for honesty, integrity, and aptitude, the Individual Defendants have exposed the Company to very expensive legal costs to defend, investigate, and pay judgment or settlement damages in the Securities Class Action.

110. As a direct and proximate result of the Individual Defendants' actions as alleged above, Acer's market capitalization has been substantially damaged, losing millions of dollars in value as a result of the conduct described herein.

111. Moreover, these actions have irreparably damaged Acer's corporate image and goodwill. For at least the foreseeable future, Acer will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that Acer's ability to raise equity capital or debt on favorable terms in the future is now impaired.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

112. Plaintiff incorporates the allegations herein by reference.

113. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress the Individual Defendants' breaches of fiduciary duties and other violations of the law.

114. Plaintiff is a stockholder of Acer, was a stockholder of Acer at the time of the wrongdoing alleged herein, and has been a stockholder of Acer continuously since that time.

115. Plaintiff will adequately and fairly represent the interests of the Company and its stockholders in enforcing and prosecuting its rights.

116. At the time of the filing of this complaint, the Acer Board consists of the following five individuals: Aselage, Schelling, Griffin, Dunn, and Amello.

117. As a result of the facts set forth herein, Plaintiff has not made any demand on the Acer Board to institute this action against the Individual Defendants. Such a demand would have

been a futile and useless act with respect to each and every one of the current members of the Board because they are incapable of making an independent and disinterested decision to institute and vigorously prosecute this action.

DEMAND IS FUTILE AS TO ALL DIRECTOR DEFENDANTS BECAUSE THEY EACH FACE A SUBSTANTIAL LIKELIHOOD OF LIABILITY

118. The Individual Defendants all face a substantial likelihood of liability for their individual misconduct. Defendants Aselage, Schelling, Griffin, Dunn, and Amello were directors throughout the time of the false and misleading statements, and as such had a fiduciary duty to ensure that the Company's SEC filings, press releases, and other public statements and presentations on behalf of the Company concerning its business, operations, prospects, internal controls, and financial statements were accurate.

119. Moreover, as directors, defendants Aselage, Schelling, Griffin, Dunn, and Amello owed a duty to, in good faith and with due diligence, exercise reasonable inquiry, oversight, and supervision to ensure that the Company's internal controls were sufficiently robust and effective (and were being implemented effectively), and to ensure that the Board's duties were being discharged in good faith and with the required diligence and due care. Instead, defendants Aselage, Schelling, Griffin, Dunn, and Amello knowingly and/or recklessly allowed, made or authorized false and misleading statements, failed to timely correct such statements, failed to take necessary and appropriate steps to ensure that the Company's internal controls were sufficiently robust and effective (and were being implemented effectively), and failed to take necessary and appropriate steps to ensure that the Board's duties were being discharged in good faith and with the required diligence. These actions constitute breaches of the fiduciary duties of loyalty and good faith, for which the Individual Defendants face a substantial likelihood of liability. If defendants Aselage, Schelling, Griffin, Dunn, and Amello were to bring a suit on behalf of Acer

to recover damages sustained as a result of this misconduct, they would expose themselves to significant liability. This is something they will not do. For this reason, demand is futile as to defendants Aselage, Schelling, Griffin, Dunn, and Amello.

120. Further, defendant Schelling is incapable of considering a demand to commence and vigorously prosecute this action because he faces additional substantial likelihood of liability as he is a named defendant in the Securities Class Action. Additionally, defendant Schelling is not independent because his principal income comes from his employment with Acer. In 2018 alone, defendant Schelling received $550,000 from the Company in compensation.

DEMAND IS EXCUSED AS TO THE AUDIT COMMITTEE DEFENDANTS BECAUSE AS MEMBERS OF THE AUDIT COMMITTEE THEY FACE A SUBSTANTIAL LIKELIHOOD OF LIABILITY

121. As members of the Audit Committee during the Relevant Period, the Audit Committee Defendants participated in and knowingly approved filing of false financial statements and allowed the Individual Defendants to repeatedly make other false and misleading statements to the investing public. More specifically, as members of the Audit Committee, the Audit Committee Defendants were obligated to oversee and monitor (a) the integrity of the Company's financial statements, and (b) the Company's compliance with legal and regulatory requirements. Instead, the Audit Committee Defendants, as members of the Audit Committee, failed to ensure the integrity of the Company's financial statements and financial reporting process, the Company's systems of internal accounting and financial controls and compliance with legal and regulatory requirements, as required by the Audit Committee Charter. For this reason, demand is futile as to the Audit Committee Defendants.

COUNT I
VIOLATION OF SECTION 14(A) OF THE EXCHANGE ACT
(Against the Director Defendants)

122. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

123. The Section 14(a) Exchange Act claims alleged herein are based solely on negligence. They are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants. The Section 14(a) Exchange Act claims detailed herein do not allege and do not sound in fraud. Plaintiff specifically disclaims any allegation of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to the nonfraud claims.

124. The Director Defendants negligently issued, caused to be issued, and participated in the issuance of materially misleading written statements to stockholders which were contained in the 2019 Proxy. In the 2019 Proxy, the Board solicited stockholder votes to reelect certain of the Director Defendants to the Board.

125. The 2019 Proxy, however, misrepresented and failed to disclose, among other things, the Board's risk oversight and the Company's inadequate internal controls which facilitated the illegal behavior described herein. By reasons of the conduct alleged herein, the Individual Defendants violated Section 14(a) of the Exchange Act. As a direct and proximate result of these defendants' wrongful conduct, Acer misled and deceived its stockholders by making materially misleading statements that were essential links in stockholders following the Company's recommendation and voting to reelect the Director Defendants to the Board.

126. Plaintiff, on behalf of Acer, thereby seeks relief for damages inflicted upon the Company based upon the misleading 2019 Proxy in connection with the improper reelection of defendants Aselage, Amello, Dunn, Griffin, and Schelling to the Board.

COUNT II
BREACH OF FIDUCIARY DUTY
(Against the Individual Defendants)

127. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

128. Each of the Individual Defendants owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Acer's business and affairs.

129. Each of the Individual Defendants violated and breached his or her fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

130. The Individual Defendants' conduct set forth herein was due to their intentional or reckless breach of the fiduciary duties they owed to the Company, as alleged herein. The Individual Defendants intentionally or recklessly breached or disregarded their fiduciary duties to protect the rights and interests of Acer.

131. In breach of their fiduciary duties, the Individual Defendants failed to maintain an adequate system of oversight, disclosure controls and procedures, and internal controls.

132. In addition, the Individual Defendants further breached their fiduciary duties owed to Acer by willfully or recklessly making and/or causing the Company to make false and misleading statements and omissions of material fact and failing to disclose to investors that: (i) the Ong Trial data were insufficient to support FDA approval based on the imbalance between the study's experimental and control arms, and the severe bias and underpowering of the study; and (ii) the significant limitation of the Long-Term Observational Study in that it could not answer "whether the systematic treatment with celiprolol has an additional genuine pharmacological beneficial event; and (iii) communications from the FDA that the Ong Trial data were flawed and the limited value of the Long-Term Observational Study.

133. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

134. The Individual Defendants failed to correct and caused the Company to fail to rectify any of the wrongs described herein or correct the false and misleading statements and omissions of material fact referenced herein, rendering them personally liable to the Company for breaching their fiduciary duties.

135. The Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly engage in the fraudulent scheme set forth herein and to fail to maintain adequate internal controls. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent scheme set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to improperly engage in the fraudulent scheme and to fail to maintain adequate internal controls, even though such facts were available to them. The Individual Defendants, in good faith, should have taken appropriate action to correct the schemes alleged herein and to prevent them from continuing to occur.

136. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

137. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Acer has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

138. Plaintiff on behalf of Acer has no adequate remedy at law.

COUNT III
WASTE OF CORPORATE ASSETS
(Against Individual Defendants)

139. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

140. As a result of the Individual Defendants' failure to implement adequate internal controls to ensure that the Company's SEC filings and other public statements were not misleading, Acer is subject to the Securities Class Action. The Individual Defendants have caused Acer to waste its corporate assets by forcing the Company to expend valuable resources in defending itself in the ongoing litigation, in addition to any ensuing costs from a potential settlement or adverse judgment.

141. As a result of this waste of corporate assets, the Company has been damaged and the Individual Defendants are each liable to the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Declaring that Plaintiff may maintain this derivative action on behalf of Acer and that Plaintiff is a proper and adequate representative of the Company;

B. Awarding the amount of damages sustained by the Company as a result of the Individual Defendants' breaches of fiduciary duties and violations of the federal securities laws;

C. Granting appropriate equitable relief to remedy Individual Defendants' breaches of fiduciary duties and other violations of law;

D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees and costs and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: March 17, 2020

Respectfully Submitted,

LEVI & KORSKINSKY LLP

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CERTIFICATE OF SERVICE

I, Shannon L. Hopkins, certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on March 17, 2020.

Dated: March 17, 2020

/s/Shannon L. Hopkins
Shannon L. Hopkins